

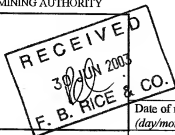
CID 237  
PATENT COOPERATION TREATY

From the:  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

REH  
CIB

To:

F B RICE & CO  
605 Darling Street  
BALMAIN NSW 2041



PCT

WRITTEN OPINION  
(PCT Rule 66)

Applicant's or agent's file reference 112925		Date of mailing (day/month/year) 30 JUN 2003 REPLY DUE within TWO MONTHS from the above date of mailing
International Application No. PCT/AU03/00229	International Filing Date (day/month/year) 24 February 2003	Priority Date (day/month/year) 22 February 2002
International Patent Classification (IPC) or both national classification and IPC Int. Cl. <sup>7</sup> A61F 11/04		
Applicant COCHLEAR LIMITED		

- This written opinion is the first drawn by this International Preliminary Examining Authority.
- This opinion contains indications relating to the following items:
  - ☒ Basis of the opinion
  - ☐ Priority
  - ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - ☐ Lack of unity of invention
  - ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - ☐ Certain documents cited
  - ☐ Certain defects in the international application
  - ☒ Certain observations on the international application
- The FINAL DATE by which the international preliminary examination report must be established according to Rule 69.2 is:  
22 June 2004
- The applicant is hereby invited to reply to this opinion.  
 When? See the Reply Due date indicated above. However, the Australian Patent Office will not establish the Report before the earlier of (i) a response being filed, or (ii) one month before the Final Date by which the international preliminary examination report must be established. The Report will take into account any response (including amendments) filed before the Report is established.  
 If no response is filed by 1 month before the Final Date, the international preliminary examination report will be established on the basis of this opinion.  
 Applicants wishing to have the benefit of a further opinion (if needed) before the report is established should ensure that a response is filed at least 3 months before the Final Date by which the international preliminary examination report must be established.
- How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3.  
For the form and the language of the amendments, see Rules 66.8 and 66.9.
- Also For an additional opportunity to submit amendments, see Rule 66.4.  
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4bis.  
For an informal communication with the examiner, see Rule 66.6.

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**WRITTEN OPINION**

International application No.  
PCT/AU03/00229

**I. Basis of the opinion**

1. With regard to the elements of the international application:\*

- ☒ the international application as originally filed.
- ☐ the description, pages , as originally filed,  
pages , filed with the demand,  
pages , received on with the letter of
- ☐ the claims, pages , as originally filed,  
pages , as amended under Article 19,  
pages , filed with the demand,  
pages , received on with the letter of
- ☐ the drawings, pages , as originally filed,  
pages , filed with the demand,  
pages , received on with the letter of
- ☐ the sequence listing part of the description:  
pages , as originally filed  
pages , filed with the demand  
pages , received on with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.  
These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed"

WRITTEN OPINION

International application No.

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III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos: 47 and 48.

because:

☐ the said international application, or the said claim Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claim Nos. 47 and 48

2. A written opinion cannot be drawn due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

WRITTEN OPINION

International application No.  
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V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1 - 41, 43 - 45	YES
	Claims 42, 46, 49	NO
Inventive step (IS)	Claims 5, 7 - 34, 36, 37, 39 - 41, 44, 45	YES
	Claims 1 - 4, 6, 35, 38, 42, 43, 46, 49	NO
Industrial applicability (IA)	Claims 1 - 46, 49	YES
	Claims	NO

2. Citations and explanations

NOVELTY (N) Claims 42, 46 and 49:

D1 - US 5443493 A

D2 - US 6070105 A

D3 - US 6125302 A

D1 discloses the features of claims 42 and 46. Figures 2 and 4 of the citation show a pre-curved electrode array 12 maintained in a straight configuration by straightening member 21. As the array is inserted into the cochlea by moving button 32 the straightening member is prevented from also moving into the cochlea as it is attached to tube 26. Therefore all features of claims 42 and 46 are disclosed by D1.

D2 discloses all the features of claim 49. Figure 2D of D2 shows an electrode array 121' for insertion into a cochlea, a straightening member 138 with a portion extending beyond the proximal end of the array and the portion including a spherical member.

D3 discloses the features of claims 42 and 46. Figures 12 and 13A show a pre-curved array 10, straightening member 62 and insertion device 64. Column 7 lines 44 to 62 describes how the straightening member 62 is progressively removed as the array is advanced into the cochlea.

INVENTIVE STEP (IS) Claims 1-4,6,35,38,42,43,46,49:

Claims 42,46 and 49: As per novelty above.

Claim 43 is not considered to involve an inventive step. D1 discloses all the features of claim 43 except for the loading cartridge. However first mounting the array into a cartridge before loading into the insertion device is not considered to involve an inventive step. I consider that this difference between the claimed invention and the citation constitutes no more than a mere workshop improvement. It is an arrangement that any competent worker in the art would be expected to make directly and without difficulty and by routine steps alone. Therefore the claimed invention does not involve an inventive step.

**WRITTEN OPINION**

International application No.

**PCT/AU03/00229**

**VIII. Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. Claim 40 lacks clarity because it seems as if it should be appended to claim 39 instead of 40, as claim 40 defines that the housing is angled.

## WRITTEN OPINION

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**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

**Continuation of Box V**

D3 renders claims 1-4, 6, 35 and 38 non-inventive. Figures 12 and 13A of D3 show an electrode array that is straightened by stylet 62. The device for implanting the array includes a main body 64. Column 7 lines 44 to 62 describe how the electrode array is simultaneously pushed off the stylet and out of the main body. While no "positioning member" is explicitly disclosed, the citation describes how a "pushing or extraction force may be applied" against shoulder 17. An instrument would be used to exert this force, this instrument being the "positioning member" of claim 1. Pushing the electrode array off the stylet would also require the stylet to be held, requiring the existence of a "capture member". Therefore the citation discloses all the features of claim 1 except that the features are not connected to form "a device". However a device that merely mimics what is done by hand is not considered to be inventive. I consider that this difference between the claimed invention and the citation constitutes no more than a mere workshop improvement. It is an arrangement that any competent worker in the art would be expected to make directly and without difficulty and by routine steps alone. Therefore the claimed invention does not involve an inventive step.